

REMARKS

Claims 7-9, 15, 19-23, 29, 33, and 34 are pending in the present application.

Applicants wish to thank Examiner Rao for the helpful and courteous discussion with their undersigned Representative on April 11, 2007. During this discussion, an amendment and arguments to address the enablement rejection was discussed. The content of this discussion is believed to be reflected in the amendments and remarks set forth herein.

The rejection of Claims 7-17, 19-31, and 33-34 under 35 U.S.C. §112, first paragraph (enablement), is obviated in part by amendment and traversed in part.

The present invention provides, *inter alia*, an isolated nucleic acid encoding an alkaline protease having an amino acid sequence which is at least 90% homologous to an amino acid sequence of either SEQ ID NO: 1 (see Claim 7) or SEQ ID NO: 2 (see Claim 21), wherein said isolated alkaline protease has alkaline protease activity.

In the outstanding Office Action the Examiner has maintains that the specification fails to enable the scope of homologs defined by “at least 90% homologous to an amino acid sequence of SEQ ID NO: 1 (or 2).” Applicants continue to disagree.

The Examiner summarizes his position alleging that the specification does not establish “(A) regions of the polynucleotide structure which may be modified without affecting its activity of encoding the polypeptide having the specific protease activity; (B) the general tolerance of polynucleotides encoding such proteases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleotide on the polynucleotide encoding said protease with an expectation of obtaining the desired biological

function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.”

In response to the foregoing, Applicants submit that original Claim 1 and the specification at page 2, line 26 to page 3, line 13 provides several additional physicochemical properties by which the claimed enzyme is characterized. Accordingly, Claims 7 and 21 have been amended to change the claims from the nascent recitation of the sequence, the degree of homology, and required activity to further recite specific physicochemical properties. Applicants submit that in view of these physicochemical properties, the skilled artisan would be able to identify and evaluate any candidate polynucleotide sequence encoding proteins within the scope of the claimed invention without undue experimentation.

Specifically, in addition to encoding an alkaline protease having an amino acid sequence which is at least 90% homologous to an amino acid sequence of either SEQ ID NO: 1 (see Claim 7) or SEQ ID NO: 2 (see Claim 21), that alkaline protease must have the following physicochemical properties:

- (i) Acting pH range acting over a wide pH range of 4-13 and exhibiting, at a pH of 6-12, 80% or more the activity at the optimum pH;
- (ii) Stable pH range being stable over a pH range of 6-11 when treated at 40°C for 30 minutes;
- (iii) Isoelectric point of approximately 8.9-9.1; and
- (iv) Effect of a fatty acid casein-degrading activity not being inhibited by oleic acid

MPEP § 2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that determining what sequences fall within or outside the scope of the presently claimed invention would be readily apparent to the skilled artisan *without* undue experimentation when these claims are read in view of the specification, as well as the knowledge generally available in the art. The Examiner's attention is drawn to pages 5-7, which provides a description of the scope of homology permissible in the claimed alkaline protease. At pages 7-12, Applicants describe the method by which the claimed amino acid sequences may be cloned, expressed, and isolated. Moreover, at pages 14-45, Applicants provide a detailed example of how the skilled artisan may clone, express, and characterize any sequence variant to assess its standing with respect to the claimed invention.

MPEP §2164.04 states:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In view of the specifically highlighted pages in the specification (supra), Applicants submit that they have met their burden to enable the skilled artisan to obtain a alkaline protease having an amino acid sequence which is at least 90% homologous to an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 2, wherein said isolated alkaline protease has alkaline protease activity and wherein the alkaline protease exhibits the claimed physicochemical properties which include structural as well as functional requirements.

Based on the foregoing, Applicants submit that the present claims are fully enabled by the specification and the common knowledge available in the art and as such withdrawal of this ground of rejection is requested.

Applicants respectfully request that the obviousness-type double patenting rejections of Claims 7-17, 19-31, and 33-34 over: (a) Claims 4-20 of U.S. 6,376,227, and (b) claims drawn to "a gene" in co-pending Application Nos. 10/456,479, 10/820,712, 10/820,714, 11/235,249, and 11/318,576, be held in abeyance until an indication of allowable subject matter in the present application. If necessary, a terminal disclaimer will be filed at that time. Until such a time, Applicants make no statement with respect to the propriety of this ground of rejection.

Applicant submits that the application is now ready for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)